

FORM 10

MINUTES OF PUBLIC HEARING South Dakota Board of Pharmacy

The South Dakota Board of Pharmacy convened at 1:04 p.m. CDT on September 1, 2020, via zoom due to the coronavirus pandemic.

The purpose of the meeting was to conduct a public hearing on the proposed rules of the South Dakota Board of Pharmacy, numbered §§ 20:51:01, 20:51:02, 20:51:03, 20:51:04, 20:51:05, 20:51:06, 20:51:07, 20:51:13, 20:51:14, 20:51:15, 20:51:16, 20:51:17, 20:51:19, 20:51:20, 20:51:21, 20:51:22, 20:51:23, 20:51:24, 20:51:25, 20:51:27, 20:51:28, 20:51:29, 20:51:30, and 20:51:35 adopted under the authority of SDCL 36-11-11.

Hearing Officer/Chair: Leonard Petrik, Board President.

Members of the Board in Attendance: Leonard Petrik, Board President; Diane Dady, Cheri Kraemer, Tom Nelson, and Dan Somsen.

Other Board Staff in Attendance: Executive Director, Kari Shanard-Koenders; PDMP Director, Melissa DeNoon; Inspectors, Tyler Laetsch, Paula Stotz, and Carol Smith; and Secretary, Beth Windschitl.

Others in Attendance: Sara Redler, Christine Berg, Joel Kurzman, Tim Engel, David McVey, Jessica Strobl, Amanda Kuhn, Amanda Bacon, Jessica Adams, Lauren Paul, Justin Manning, Bill Van Camp, Rich Palumbo, Mark Gerdes, Lorri Ollerich, and Bob Mercer.

Chair Petrik welcomed attendees, read the board mission statement, and initiated attendee introductions. A voice roll call of board members was taken, all members were present, and a quorum was declared. Member Dady made a motion to approve today's agenda, member Kraemer seconded, a voice roll call taken; motion passed (5-0). Dady made a motion to approve the July 30th, 2020 Board Meeting Minutes, member Somsen seconded, a voice roll call taken; motion passed (4-0).

Executive Director Shanard-Koenders explained the rules promulgation process/activities completed by the board and presented a synopsis of the proposed rule changes at hand. The Chair opened the floor for public comment noting each person was allotted a maximum of five minutes to speak and responses to comments would be addressed at a later date.

COMMENTS

A. Oral Testimony

Five individuals testified.

1. Timothy M. Engel, SD State Medical Association General Counsel Representative

Mr. Engel reiterated the written recommendations provided by the SDSMA requesting the following changes to the proposed rules. In **20:50:05:23**. Distribution of dialysate by manufacturer or the manufacturer's agent to a patient / exempt from pharmacy licensure. SDSMA recommends that the rule be further revised to make clear a prescription is required for dialysates to be shipped directly to the patient's home.

Further, he recommended changes to **20:51:28:05**. Record keeping and reporting requirements as SDSMA does not oppose a requirement to report immunizations to SDIIS but does oppose the repeal of the requirement to report an immunization to the patient's primary health provider.

William Van Camp, Jr., Olinger Law Firm, representing Baxter Healthcare on rule **20:50:05:23**.
Distribution of dialysate by manufacturer or the manufacturer's agent to a patient / exempt from pharmacy licensure

Mr. Van Camp clarified that dialysate or dialysis devices are delivered only upon receipt of a prescription order issued by a licensed physician and only if an order from a licensed pharmacy is transmitted to the manufacturer or the manufacturer's agent. Baxter proposed alternate wording to add the prescription order for this rule to satisfy the SDSMA concerns. Mr. Van Camp also requested that dialysis devices be added to the proposed rules, which he included in the recommended changes provided.

2. Lauren Paul, Sr. Director Pharmacy Regulatory Affairs – CVS Health

Ms. Paul referenced the CVS Health comments which recommended/requested several changes to the proposed rules (see written comments) such as expanding technician activities to add immunizations and accepting orders, expansion of telepharmacy rules for no requirement for pharmacy desert, emergency fills, and ekit and other Long Term Care changes.

3. Jessica Adams, Pharm.D. – Telepharm

Ms. Adams referenced the written comments from Telepharm which recommended/requested changes to the proposed rules: **20:51:30**. Telepharmacy section - expanding the existing telepharmacy regulations to no longer demonstrate there is limited or no access to pharmacy services in an area **20:51:30:02**, no longer require a telepharmacy technician have work experience **20:51:30:12**, and frequent, mandatory inspections **20:51:30:17**.

4. Jessica Strobl, Pharm.D., Director of Pharmacy Services – Lewis Pharmacies

Ms. Strobl recommended/requested a change to **20:51:23:01**. Transfer of original prescription information permitted to allow the use of a facsimile for the purpose of transferring prescriptions. Her written comments proposed wording to be incorporated to allow this. She discussed that transfers of original prescriptions be allowed via facsimile as this mode of transfer contains more than the required information needed to transfer a prescription and provides information in a thorough fashion and is a safer, quicker, easier way to communicate a prescription transfer to another pharmacy.

5. Tyler Laetsch, Board Inspector, presented the Legislative Research Committee's (LRC) *style* and *form* changes to the proposed rules and the areas which were changed based upon comments by the LRC in addition or in response to the form and style changes as provided. There were no comments regarding the information presented.

B. Written Testimony

1. Lorri Walmsley, Director Pharmacy Affairs - Walgreens

Walgreens recommended/requested the following changes to the proposed rules:

20:51:05:15.01. Identification required for controlled drug prescription

Remove signage requirement (The pharmacy shall post a notice to the public that states “No prescription for a controlled drug may be sold without verification of purchaser identity”).

20:51:13:06. Remote prescription pickup sites

Rule as written limit options for potential innovative solution. Recommend board consider alternative prescription sites be allowed as an alternative form of “delivery”

20:51:14:04. Equivalent drug products

Amend to allow pharmacies to use the most current reference for equivalent drug products and not Orange Book specifically.

20:51:17:02. Procedures for distribution or dispensing drugs in automated mechanical distribution and automated prescription dispensing device

Encourage the board to allow electronic storage of information related to the product instead of on each individual drug/medicine container.

20:51:22:05. Support personnel

Suggest eliminating the enumerate list outlining the types of duties support personnel can perform and replace with suggested text - support personnel may perform any functions delegated to them by a pharmacist with the exception of those outlined in 20:51:29:21 and prohibited in 20:51:29:22.

20:51:32:02. Requirements of transferring pharmacist or intern

20:51:23:03. Requirements of receiving pharmacist or intern

Encourage the addition of pharmacy technicians to each rule allowing them to also perform transfers as currently allowed during COVID-19 emergency.

20:51:23:04. Additional requirements for controlled substances (transfers)

Add, a pharmacy technician may not participate in the transfer of a controlled substance.

20:51:25:04. Standards for counseling

Add to each counseling standard listed, the option of using alternative technology means that may be available and acceptable to the patient for counseling delivery.

20:51:28 Administration of Influenza Immunization

Requests certified pharmacy technicians have authority to administer immunizations (after completion of CPR course, immunization training program).

20:51:29:19. Ratio

Requests the board strike 20:51:29:19 and allow the pharmacist-in-charge to determine the ratio for their location.

20:51:29:21. Technician functions

Request adding the following functions that do not require clinical judgment (contacting prescribers for clarification, transferring prescriptions, accepting verbal prescriptions, technology-assisted product verification, and administration of immunization).

20:51:29:22. Tasks a pharmacy technician may not perform

Strike task #5, accept new oral prescription medication orders communicated to the pharmacy by a prescriber or the prescriber’s agent.

20:51:30. Telepharmacy

Requests board strike the language in 20:51:30:02 requiring an applicant to demonstrate to the board that there is limited or no access to pharmacy services in the community. Additional Walgreens requests the board eliminate 20:51:30:03 Ownership or control by pharmacists required.

20:51:30:10. Toll-free telephone number

Requests board strike 20:51:30:10 as long-distance charges are rare in the cellular age and having to maintain a toll-free number adds expense for business.

20:51:30:15. Requirements for prescription orders

Requests board strike 20:51:30:15 removing the restriction that technicians may not accept verbal orders for new prescriptions and allow pharmacy technicians to perform the same functions in a telepharmacy as those requested (in 20:51:31:15) for pharmacy technicians.

2. Jessica Adams, Pharm.D. – Telepharm

Telepharm recommended/requested the following changes to the proposed rules:

20:51:30. Telepharmacy

Recommends expanding the existing telepharmacy regulations to be more in line with current technologies and practices. The chapter requirements that an applicant demonstrate/prove there is limited or no access to pharmacy services in an area 20:51:30:02, a technician have work experience 20:51:30:12, and frequent, mandatory inspections 20:51:30:17, restricts telepharmacy.

3. InstyMeds, No Representative, report was presented by Tyler Laetsch

InstyMeds provided comments as it relates to regulatory guidelines pertaining to InstyMeds. InstyMeds is unclear as to whether chapters 20:15:17, 01, 01.01, 01.02, 02 addressing Automated Mechanical Distribution Devices applies to their technology (IM-MAS). InstyMeds suggests medical providers should have oversight over the dispensing process, inventory, reporting, and regulatory compliance as it pertains to IM-MAS no matter where it is located as long as it is a healthcare facility as defined in the regulations.

4. Lauren Paul, Sr. Director Pharmacy Regulatory Affairs – CVS Health

CVS Health recommended/requested the following changes to the proposed rules:

20:51:29:19. Ratio

Requests board repeal 20:51:29:19 the ratio and permit the pharmacy manager to use their professional discretion to evaluate the needs of the pharmacy and determine the appropriate number of technicians.

20:51:29:21. Technician functions

Proposes use of a pharmacist delegation model of pharmacy technician duties to enhance and optimize services. In this model, trained technicians can perform roles and tasks that do not require the professional judgment of a pharmacist. Pharmacist discretion in delegation creates control of which functions to delegate.

20:51:28 Administration of Influenza Immunization

Requests board amend proposed rules 20:51:28:01 & 20:51:28:04 to permit certified pharmacy technician who have completed both CPR training and an ACPE accredited immunization administration training program to administer immunizations in South Dakota.

20:51:30. Telepharmacy

Requests amend chapter to create a telepharmacy practice model that aligns with telepharmacy regulations in other states to avoid common regulatory pitfalls (limiting pharmacy mileage restrictions, prescription volume, practice setting restrictions...).

No specific Section Long-Term Care Pharmacy

CVS suggests the board repeal current long-term pharmacy rules while considering adoption of the language in the NABP State Pharmacy Model Act and Rules to modernize long-term care pharmacy practice.

20:51:05:20. Legend drug to be dispensed by prescription only – Refill restricted

Supports permanent adoption of Governor Noem’s Executive Order 2020-16 allowing a pharmacist to refill a prescription if there was no availability to reach a prescriber to renew a medication and requests allowing pharmacist to renew a prescription for *non-controlled legend drugs* when an effort has been made to contact the prescriber.

5. Jessica Strobl, Pharm.D., Director of Pharmacy Services – Lewis Pharmacies

Lewis Pharmacies recommended/requested the following changes to the proposed rules:

20:51:23:01. Transfer of original prescription information permitted

Requests transfers of original prescriptions be allowed via facsimile as this mode of transfer contains more than the required information needed to transfer a prescription and provides information in a thorough fashion and is a safer, quicker, easier way to communicate a prescription transfer to another pharmacy.

6. Timothy M. Engel, SD State Medical Association General Counsel Representative

SDSMA recommended/requested the following changes to the proposed rules:

20:50:05:23. Distribution of dialysate by manufacturer or the manufacturer’s agent to a patient / exempt from pharmacy licensure

SDSMA reiterates its previous informal recommendation that the rule be further revised to make clear a prescription is required in order for dialysates to be shipped directly to the patient’s home.

20:51:28:05. Record keeping and reporting requirements

SDSMA does not oppose a requirement to report immunizations to SDIIS but does oppose the repeal of the requirement to report an immunization to the patient’s primary health provider.

7. William Van Camp, Jr. , Olinger Law Firm, representing Baxter Healthcare

20:50:05:23. Distribution of dialysate by manufacturer or the manufacturer’s agent to a patient / exempt from pharmacy licensure

Mr. Van Camp clarified that dialysate or dialysis devices are delivered only upon receipt of a prescription order issued by a licensed physician and only if an order from a licensed pharmacy is transmitted to the manufacturer or the manufacturer's agent.

Executive Director Shanard-Koenders provided a synopsis of the rule change requests received which should be discussed by the Board. Based on the oral and written comments, board members further discussed changes to the proposed rules pertaining to the dialysate rules, facsimile use, immunization reporting, technician ratios/duties, telepharmacy, LRC style/form, and the correct use of terminology (physician versus practitioner).

There being no further comments, the chair requested a motion.

- Member Kraemer made a motion to approve the Board of Pharmacy proposed rule changes to include the LRC form and style changes except for the changes which were outlined by Tyler Laetsch as they varied slightly from the LRC changes. Motion was seconded by Dady, a voice roll call was taken, and motion passed (5-0).
- Member Somsen made a motion to change the proposed rules to add the transfer of prescription information via facsimile. Motion was amended to include using the rule language proposed by Lewis Pharmacies. Motion was seconded by Kraemer. A voice roll call was taken, and motion passed (5-0).
- Member Dady made a motion to change the telepharmacy inspection visits in 20:51:30:17 from weekly to a minimum of every two weeks. Motion was seconded by Somsen, a voice roll call was taken, and motion passed (5-0).
- Member Dady made a motion to approve the Baxter Health amended language and made one other change of the word physician to practitioner, for consistency. Motion was seconded by Somsen, a voice roll call was taken, and motion passed (5-0).

C. Adjournment

A motion to adjourn was made by Dady and seconded by Kraemer. A voice roll call was taken, motion passed (5-0). Meeting adjourned at 3:20 pm. CDT.